

REMARKS

This response is submitted in reply to the final Office Action mailed February 16, 2011 ("the Action"). Applicant hereby requests further consideration of the application in view of the amendments above and the comments that follow. Claims 1, 4-15, 17, 18, 20-26, 32, 62 and 66-71 are pending in the application. Claim 16 has been canceled in this response; its subject matter has been incorporated into Claim 1.

I. The 35 USC §112, Second Paragraph Rejections

The Action rejects the claims as being indefinite because the limitation "wherein each blister holds dry powder medicament and when sealed is devoid of any movable component" mis-describes the fact that the powder itself is a movable component. Applicant has amended Claims 1, 32 and 62 to clarify this recitation, e.g., to state that when sealed, it is devoid of any movable component therein other than the dry powder.

In view of the above, Applicant respectfully requests that the Examiner withdraw this rejection.

II. The 35 USC §102 Rejections

The Action cites U.S. Patent Application Pub. No. 2002/0134382 to Snow ("Snow") as an anticipatory reference for teaching the subject matter of Claims 1, 12, 25, 32, 62 and 68-70. Snow describes three layers 104, 108, 112 or respective disks 116, 132, 156 with an upper layer 104 of foil. However, the alleged concentric circles are only in the disk 132 forming the middle layer 108 and these openings 152 are square or rectangular. Further, the floor 164 is provided by the lower disk layer 112 and the floor has the same thickness or is thicker than the middle frame layer 108 (*see, e.g.*, Figure 2D of Snow). Further, the lower disk of Snow has deep, downwardly-extending concave receptacles or pockets 164a (para. 75, Figure 2D). Snow teaches away from a three-layer disk where both the top and bottom disk layers are relatively thin flexible layers on either side of a thicker (center) frame layer. Claims 1, 32 and 62 have been amended to recite that the frame is at least ten times thicker than either the floor or the ceiling layers (*see, e.g.*, page 13 of the pending application). Snow fails to teach or suggest at least this feature.

Further, Claims 4, 66, 68 and 70 have been amended to recite that the floor is planar. Snow also clearly teaches away from this feature.

In light of the above, Applicant requests that this rejection be withdrawn.

III. The 35 USC §103 Rejections

The Action rejects Claims 1, 4-11, 13-18, 20-24, 26, 32, 62, 66, 67, 69 and 71 as being obvious over WO 01/68169 to Hickey et al. ("Hickey") in view of U.S. Patent No. 7,588,030 to Ede ("Ede"). The Action cites to Hickey for teaching flexible materials but concedes that Hickey fails to teach a center rigid frame member as claimed (Action, p. 5). However, the Action then states that Ede teaches a rigid polymeric frame member 10 (Figures 1d, 5, 8 and col. 6, lines 22-23) and alleges that one of skill in the art would have made the blister pack of Hickey with the frame member of Ede "to allow for larger numbers of doses to be contained" as taught by Ede (col. 3, lines 36-40). Action, p. 6. Applicant respectfully disagrees.

Ede and Hickey propose very different dose package designs. Ede clearly requires the use of cups (inserts) in a carrier. Thus, properly combined, if one were to modify Hickey with Ede, then the resulting dose package would include the frame and the insert cups holding the dry powder. Ede clearly *teaches away* from a package that does not use the internal cups.

Further, absent the teachings of the instant application, there is no motivation to combine the isolated teachings of these different dose package designs. Ede proposes a medicament container to overcome the design restrictions of blister packs with deep drawn film (col. 1, lines 54-56) using cup-like inserts (col. 1, lines 32-35) and notes that the pockets can have depth to width ratios for increased doses to be contained for a given area (col. 3, lines 36-40).

However, this is not sufficient motivation to modify Hickey, which proposes a very different design including thin-film piezoelectric material that forms part of and vibrates the blisters. The package design is constrained by many factors and affects cost as well as dose filling protocols and opening of the dose containers. One of skill in the art would not have been motivated to modify the blister design of Hickey with the design of Ede as alleged, as each is directed to a very different dose package design. For example, Applicant submits that Ede is not directed to vibration designs and using the cup and carrier design would appear to negatively impact the blister vibration configuration of Hickey which proposes a thin film piezoelectric material that forms the blister pocket.

Applicant respectfully submits that the fact that isolated elements of the claimed subject matter can be found in different prior art references is not dispositive. It is the claimed combination of features that this the proper basis of review. One of skill in the art would not have modified Hickey with the frame of Ede as alleged to arrive at the claimed subject matter as each operates in very different ways including drug dispersement (how the drug exits the blister) and opening of the blister/dose container.

Claims 25, 68 and 70

Claims 25, 68 and 70 stand rejected as being obvious of Hickey and Ede as applied above and further in view of U.S. 2007/0181124 to Casper ("Casper"). The Action concedes that Hickey and Ede fail to teach the angled sidewalls. However, the Action cites to Casper for this feature and alleges that this feature is obvious as being a design choice that only requires a change in shape of a component and would function equally as well. Applicant respectfully disagrees. Figures 5A and 6A of Casper illustrate examples of blisters that appear to be formed of a thin material, not a rigid through aperture in a center frame. One of skill in the art would not have modified Hickey and Ede to change the frame of Ede. Indeed, because Ede requires an insert, the use of straight walls would appear to be required for operability. Applicant respectfully submits that, absent the teachings of embodiments of the present invention, there is no motivation to modify Ede, much less Hickey and Ede as alleged. This feature is not a mere change in shape with no change on function as alleged by the Action; rather, the taper can provide benefits in manufacturing a molded body and the like and may also have some influence on compaction of the drug in the dose container. Applicant respectfully submits that Claims 25, 68 and 70 are patentable over the cited prior art.

IV. New Claim

Applicant has added new Claim 72 that recites that the center frame member is at least 15 times greater than the thickness of the flexible layers, that the floor is planar (*see, e.g.*, p. 13 of the specification), that the walls of the frame member taper (angle), and that there are two concentric rows of through-apertures in the center frame member. Applicant respectfully submits that Claim 72 is patentable over the cited prior art.

CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, she is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,



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CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on March 29, 2011.

Signature: _____

Cara L. Rose

